Exhibit B

GENERAL REPORT OF BARRY SCHLAFSTEIN, M.D., F.A.C.O.G. REGARDING THE TVT and TVT-O

The following is my general report regarding the TVT and TVT-O polypropylene mid-urethral slings. The opinions expressed are based on my education, training, knowledge, experience, review of medical literature, attendance at medical meetings, and discussions with colleagues, and is based on information I have reviewed as part of my continuing medical review, the materials cited in this report, and information I have available to me, as set forth in Exhibit A to this report. It is my practice to regularly review medical information, attend and/or participate in medical meetings and consultations with my colleagues as part of my continuing medical education and experience. Accordingly, I reserve the right to add to or modify the opinions set forth in this report as information becomes available to me. All of my opinions expressed in this report are held to a reasonable degree of medical and scientific certainty.

I. Background, Training and Experience

In 1991, I completed my chief residency at The Johns Hopkins Hospital, in Baltimore, Maryland, after completing my internship and residency also at The Johns Hopkins Hospital. I obtained my M.D. degree, and received AOA membership honors from the University of Miami School of Medicine in 1987. In 1983, I received my B.S. degree, with honors in Nutritional Sciences from Cornell University in Ithaca, New York. I am board-certified by the American Board of Obstetrics & Gynecology in both Obstetrics & Gynecology (1993) and in Female Pelvic Medicine & Reconstructive Surgery (2013). I am licensed to practice medicine in Georgia, Florida and Maryland. I am a Fellow in the American College of Obstetrics & Gynecology, a member of the American Urogynecological Society (AUGS), The Georgia Obstetrical and Gynecological Society, and various other medical organizations. After

completing my rotation as Chief Resident at Johns Hopkins in 1991, I joined a private practice specializing in obstetrics and gynecology in Miami, Florida, and in 1996 joined a private OB/GYN practice in Savannah, Georgia. In 1997, I started my own practice specializing in OB/GYN and sub specializing in Female Pelvic Medicine and Reconstructive Surgery (aka. UroGynecology) in Savannah, Georgia, and have continued that practice to the present time. My practice includes general gynecological care, pelvic floor reconstruction, treatment of urinary incontinence and female pelvic organ prolapse, and 3D laparoscopic gynecological surgery. Since 2013, I have also served as Clinical Assistant Professor for the Medical College of Georgia. Because of my training and expertise, I am often referred patients by my colleagues, particularly when surgery is needed to treat complicated gynecologic maladies, and am often asked to instruct other obstetrician-gynecologists in the specialized area of female pelvic medicine and reconstructive surgery. My education and training is set forth in my curriculum vitae attached to this report as Exhibit B which also includes some of my past publications and presentations.

As a result of my training and education, I am aware of and can attest to how physicians are trained and what information is provided during such training. Moreover, because of my continuing medical education, review of medical literature, discussions with colleagues, attendance and participation in medical meetings and teaching other physicians, I am familiar with and can attest to how physicians obtain information that they rely on in performing surgical procedures, and the manner in which they apprise themselves of advances in medicine relevant to the practice of pelvic medicine. I have studied, seen and experienced, and thus can testify to, the various revolutionary innovations in this area of medicine which have improved available

medical options for treatment of pelvic floor dysfunction and which have improved the quality of life available to women who suffer from these conditions.

I have substantial experience in treating pelvic floor dysfunction, including both non-surgical and surgical treatment of pelvic organ prolapse (POP) and incontinence, including specifically stress urinary incontinence (SUI). In treating conditions associated with pelvic organ prolapse (POP), I have prescribed non-surgical treatments including the use of pessaries, behavior modification, and physical therapy. Surgical options I have performed in treating POP have included: native tissue colporrhaphy, mesh augmented colporrhapy, sacrospinous apical vaginal vault suspension, and sacrocolpopexy: Consequently, I can provide testimony as to the relative risks and benefits of such procedures, the relative efficacy of such procedures, potential complications of such procedures, how patients respond to such treatments, and the relative satisfaction patients have with their respective treatments.

With respect to the treatment of SUI, non-surgical options that I have administered and/or prescribed include: Pelvic floor muscle training, pessary use, and rarely the use of medication. Surgical procedures for SUI that I have performed at various times in my career include: anterior colporrhaphy, high Kelly urethral plication, Burch colposuspension, mid-urethral sling procedures utilizing synthetic mesh, and urethral bulking agents.

I have implanted various manufacturers' synthetic mesh products throughout my practice. I have performed more than 630 trans-vaginal procedures. I have also utilized Gynemesh PS Prolift and Prolift +M in treating POP. I am familiar with the substantial body of peer-reviewed published medical literature regarding Prolift mesh products (including Gynemesh PS, Prolift, and Prolift+M), which demonstrate the safety and efficacy of these products and on which I rely for my opinions that these products are safe and effective for treating POP. My preferred choice

for treating SUI has been and continues to be Ethicon's TVT-O, TVT-Abbrevo, and TVT-Exact inasmuch as I believe them to be safe and effective products for surgically treating this condition. I am familiar with the TVT-R product as well and the substantial body of peer-reviewed published literature regarding the TVT products which demonstrate that these products are safe and effective in treating SUI. I have implanted more than 950 TVT products listed above.

It is my opinion that synthetic macroporous polypropylene mid-urethral slings and in particular the TVT Prolene polypropylene slings referenced above are safe and effective, are not unreasonably dangerous, and are currently considered to be the gold-standard and standard of care for the treatment of SUI. This opinion is not only confirmed in numerous published, peer-reviewed medical articles, but also by numerous professional societies, including AUGS, AUA, SUFU, IUGA, ICS, NICE and ACOG. Among these organizations' focus, is the specialized treatment of pelvic disorders, and they are largely responsible for establishing recommended and standard of care practice in the treatment of such disorders. As a result, their guidelines, position papers and recommendations are routinely relied upon by physicians and surgeons, including myself, who specialize in treating pelvic disorders. I consider these organizations to be highly regarded and respected in my specialized field of practice. I often refer to and rely upon publications produced by these organizations in forming treatment plans for my patients, as do many of my colleagues. These materials are often cited as reliable sources for information relating to current medical thought and treatment.

In addition to utilizing the Ethicon products mentioned above, I have also managed complications associated with pelvic mesh procedures, often involving products manufactured by other device manufacturers. I can, therefore, testify regarding the contributing causes and appropriate treatments for such complications.

Similarly, because I have been trained to perform many of the procedures available to treat pelvic floor disorders, I understand, and, if asked, can attest to the advantages and potential complications associated with each procedure, and how to avoid or minimize the risks of such complications, if possible, and how best to approach resolution of complications when they do occur.

II. Consulting Fees and Testimonial History

I am paid $500.00 per hour for my time in these cases.

I have not testified as a retained expert witness in any matters in the past 4 years.

III. Materials Reviewed in Compiling this Report

In addition to the materials previously referenced in this report which serve as the basis for my opinions in this case, I have also reviewed the IFUs and Surgical Technique Guide for Ethicon's various mesh devices, as well as Surgeon's Resource Monographs, Professional Education slides, DVD's, animations and surgical videos, Patient Brochures, and other professional education materials relating to Ethicon's mesh devices, including the devices specifically at issue in this case.

IV. General Information

The urinary bladder functions to contain and store urine until there is a convenient time to void or expel this fluid waste from the body. Regular leakage of urine prior to such appropriate time is universally undesired, and is referred to as urinary incontinence. Urinary incontinence is at a minimum a nuisance, but quite often at can be distressing, disabling, and can in some instances lead to severe infection. While the problem is costly to society as a whole, it is particularly difficult for the individual patient and her family, and is a leading cause of nursing home admission in the elderly.

Female Urinary Incontinence

In the female there are two main categories of urinary incontinence: genuine stress urinary incontinence (GSUI), and overactive bladder (OAB). GSUI is characterized by leakage of urine with laugh, cough, sneeze, running, jumping, and exercise. OAB is generally distinguished by urinary urgency, leaking on the way to the bathroom; frequency, voiding more than seven times during the day, or more often during the day than is considered convenient; and nocturia, getting up on one or more occasion at night to void. Along with a thorough history and a focused physical examination, a special office test called urodynamics can help distinguish between these two main causes of female urinary incontinence. Although some women will have a combination, it is indeed important to distinguish between these two causes of incontinence because treatment will differ. (Jain P, Jirschele K, et al Int Urogynecol J2011;22 22:923-32)

GSUI is caused by weakness of the sub-urethral support structures, an acquired anatomic defect. This can occur as a result of childbirth, menopause, aging, and genetic factors. Often treatment is surgical, as is typical with other anatomic defects in the body such as hernias. From the early 1900s to the mid 1990s over 100 different operations have been described in the medical literature to treat GSUI, none of which ever provided a consistently excellent, consensus gold standard result.

Mid-Urethral Slings

Developed in Europe in the mid 1990's, and based on *The Integral Theory of Female Urinary Incontinence* proposed by Petros and Ulmsten (*Acta Obstet Gynecol Scand.* 1990:69 (Suppl 153)), the mid-urethral tension free sling, involves placement of a thin mesh sling under the urethra, allowing restoration of the sub-urethral anatomic support. The technique has proven

to be minimally invasive, generally takes less than 30 minutes to perform, is very safe, and remarkably effective in restoring urinary continence to the female suffering from GSUI. It is extremely important for the implanting surgeon to be skilled in this procedure, as proper tensioning and precise mid-urethral positioning of the mesh sling is paramount for success. The Type I (Amid PK Hernia 1997;1:15-21) monofilament, light weight, loosely knit polypropylene mesh used in this procedure is pre-sterilized, permanent, strong, and virtually inert to infection when properly placed (Cosson M Int Urogyncol J 2003). Details of the Gynecare TVT procedural techniques can be reviewed in the product Instructions for Use (IFU) booklets. A key feature of the Gynecare TVT line of products is that in all of the procedures needle entry commences through a small vaginal incision at the level of the mid-urethra.

General advantages of mid-urethral slings compared to Fascial Slings and Burch colpo-suspensions include: shorter operative time, the ability of the procedure to be performed in an outpatient setting under local anesthesia, minimization of an atomic distortion, and decreased incidents of post operative voiding dysfunction. As evidenced in a 2011 Cochrane review (Ogah J, Cody DJ, et al Neurourol Urogyn 2011;30:284-91) efficacy and safety of mid-urethral slings categorically have proven comparable and often favorable to other commonly performed procedures used to treat GSUI. Specific consideration given to comparison with fascial slings suggest that mid-urethral slings are as effective, with shorter operative time, less voiding dysfunction, and less de Novo urge incontinence. With regard to Burch colpo-suspension, mid-urethral slings are as, if not more effective, with shorter operative time, quicker return to voiding, and shorter overall recovery time (Ward K, Hilton P, BMJ 2002; 325:67-70). In the above Cochrane review (Ogah J, Cody DJ, et al Neurourol Urogyn 2011;30:284-91) it is also noted that monofilament tape (as in the TVT line) have higher cure rates and fewer erosions than

multifilament tapes. Also with regard to retro-pubic tapes, needle route from the 'bottom' (the mid urethral vaginal incision) to top is more effective then top to bottom route.

Several systematic reviews and meta-analyses support the use of the TVT slings and demonstrate that they are safe, effective, and the most studied of the various slings available. (Novara G, et al. Eur Urol. 2010;58:218-38; Cox A, et al. Nat Rev Urol. 2013; 10:78-89; Committee on Practice Bulletins—Gynecology and the American Urogynecologic Society. ACOG Practice Bulletin No. 155. Obstet Gynecol. 2015; 126:e66-81; Ford AA, et al. Cochrane Database Syst Rev. 2015 Jul 1;7:CD006375.) There is a multitude of long term data available on the macroporous TVT mesh. (Tommaselli GA, et al. Int Urogynecol J. 2015; 26:1253-68; Athanasiou S, et al. Int Urogynecol J. 2014; 25:219-25; Svenningsen R, et al. Int Urogynecol J. 2013; 24:1271-8; Serati M, et al. Eur Urol. 2013; 63:872-8; Serati M, et al. Eur Urol. 2012; 61:939-46).

It is extremely important for the implanting surgeon to be skilled in these procedures, as proper dissection, precise mesh placement, and correct tensioning of the mesh implant is of paramount concern for a successful result. Details of the TVT/TVT-O procedural techniques can be reviewed in the product Instructions for Use (IFU), and other professional education materials provided by Ethicon which are listed in Exhibit A. In my opinion these materials adequately warn of potential risks of the devices.

The patient for whom I recommend evaluation and surgical treatment for stress urinary incontinence includes: the woman who complains of regularly wearing a pad or adult diapers, is limited in her daily activities, or is carrying extra clothes and undergarments in her purse due to this condition, and who has failed (previously mentioned) nonsurgical measures. In the appropriately screened and selected patient, after a verbal and visual explanation of the

procedure, and after appropriate informed consent, I will offer treatment with a TVT mid-urethral sling. Wherever possible we have maintained close ongoing surveillance of such patients after their sub-urethral sling procedure. Although as yet unpublished, our outcomes to date, have been favorable. The overwhelming majority of such patients have expressed extreme satisfaction with their experience, and not infrequently the results have been enthusiastically described as 'life- changing'.

It is important to recognize that all surgical options for treating SUI, including mid-urethral slings, carry risks of post-surgical complications. For example, abdominal procedures, such as the Burch or MMK, can be more morbid than transvaginal surgery, such as mid-urethral slings, because entry into the abdominal/peritoneal cavity is required, which can have significant, and in some instances life-threatening risks, including, among others: major vessel or visceral injury, abdominal wound infection, abdominal hernia, adhesion formation, ileus, and small bowel obstruction. Autologous fascial slings require harvesting a facial graft from a separate anatomic site on the patient's body, such as the upper thigh or lower abdomen. These non-pelvic areas can become the site of hematoma, infection, wound dehiscence, hernia, and subsequent chronic pain.

Laparoscopic and robotic surgeries also require entry into the abdominal peritoneal cavity, and are associated with the risks described above for abdominal surgery, as well as additional risks associated with steep Trendelenburg positioning, CO2 insufflation, and trocar, instrument, and energy related injury.

Dyspareunia and chronic pelvic pain are known and accepted risks associated with all pelvic surgeries, and can be transient or chronic nature. Moreover, dyspareunia with or without pelvic surgery are very common complaints in women, including those with SUI. It has been

reported that up to 64% of sexually active women attending urogynecology clinics suffer from female sexual dysfunction. (Dietz V, Maher C. Pelvic organ prolapse and sexual function. Int Urogynecol J. 2013 Nov; 24(11):1853-7.).

Regardless of etiology, dyspareunia can be a very difficult condition to treat as it is often multi-factorial, involving vaginal atrophy, decreased libido, partner issues, and other causes, and may have a significant psychological component.

It is my understanding that litigation-related claims have been made that polypropylene mesh such as that used in the TVT and TVT-O degrades in situ, contracts, results in particle loss, and is carcinogenic, and that these conditions cause clinical injury to patients in whom such mesh is implanted. I am aware of no clinical data demonstrating that such conditions occur, and certainly there is no accepted, reliable data suggesting that even if such conditions exist, they have any clinical significance whatsoever. In fact, a recent study from the Mayo Clinic, undermines these claims entirely. See Linder B., et.al., Evaluation of the local carcinogenic potential of mesh used in the treatment of female stress urinary incontinence, Int Urogynecol J. 2016.

Given the number of patients in which polypropylene mesh has been implanted, as well as the voluminous studies and analyses and trials evaluating such pelvic mesh products, if any such conditions were occurring with any frequency and clinical significance, I would certainly expect published reports to exist. They do not. If these claims had any basis in science and medicine, I would not expect the most prestigious and respected professional organizations which govern the standards of gynecologic and urologic treatment of pelvic floor dysfunction, such as AUGS, AUA, IUGA and ACOG to acknowledge polypropylene mid-urethral slings as the gold standard for treating SUI. Assertions that these devices were "unreasonably dangerous"

or "defective" as I understand are being alleged by some plaintiffs' witnesses, are completely inconsistent with the position statements of these societies, the voluminous peer-reviewed published data relating to polypropylene pelvic mesh and my own clinical experience. It is my opinion that mesh products for treatment of SUI provide an important, safe and effective option for treating SUI. And the data referenced and reflected in Exhibit A bear this out and support my opinion.

Physician Training

In addition to my clinical experience implanting TVT products, I also previously served as a clinical consultant for Ethicon for over five years. As a Gynecare pelvic floor faculty member for the United States South East Prof Ed Region my responsibilities included: didactic lecturing, pelvic cadaver training, and live observational clinical demonstration on the use of these products. Our courses were tightly structured, and close attention was paid to the aptitude of each attending student. Appropriate indications for the use of these products, data regarding the efficacy and safety, complications, and our own unique experiences were thoroughly reviewed with attendees during these courses. Students were given access to, and encouraged to familiarize themselves with the unique Instructions for Use (IFU) booklet for each product. Attendees had excellent and adequate access to perform the procedures, often multiple times, on individual pelvic cadavers during such courses. Students were encouraged to seek further training and/or proctoring, if it was felt necessary, in order to safely perform these procedures after completion of the course. The responsibility for credentialing physicians to perform such procedures is under the domain of their respective and appropriate medical staff and hospital credentialing bodies. Color informational brochures, written in layman's terminology, are

provided by the company to physicians who desire their use to aid in the preoperative patient educational process.

I reserve the right to amend my opinions if further facts and/or information necessitate supplementation.

Barry Schlafstein MD, FACOG